

Board of Pharmacy

Initial Statement of Reasons

Subject Matter of Proposed Regulation: Requirements for Pharmacies that Compound Medications

Sections Affected: Repeal sections

16 CCR 1761.1

16 CCR 1761.2

Add sections

16 CCR 1735

16 CCR 1735.1

16 CCR 1735.2

16 CCR 1735.3

16 CCR 1735.4

16 CCR 1735.5

16 CCR 1735.6

16 CCR 1735.7

16 CCR 1735.8

Amend sections

16 CCR 1751

16 CCR 1751.1

16 CCR 1751.2

16 CCR 1751.3

16 CCR 1751.4

16 CCR 1751.5

16 CCR 1751.6

16 CCR 1751.7

16 CCR 1751.8

Specific Purpose of the Proposed Changes:

The Board of Pharmacy proposes to repeal sections 1716.1 and 1716.2, 1751.01, 1751.02; add sections 1735, 1735.1, 1735.2, 1735.3, 1735.4, 1735.5, 1735.6, 1735.7, 1735.8; and amend sections 1751, 1751.1, 1751.2, 1751.3, 1751.4, 1751.5, 1751.6, 1751.7, and 1751.8 of Division 17 of Title 16 of the California Code of Regulations.

The purpose for repealing the above sections is to remove duplication between Article 4.5 and Article 7 and to reorganize Article 7 to make it consistent with Article 4.5. These requirements are incorporated into section 1735.2

The purposes for adding the above sections is to address, among other items, the strength, efficacy and quality in compounding, as well as to require a quality assurance program for general compounding. Currently, there are no provisions that either define these items for general compounding or set any parameters established in the Pharmacy law (Business and Professions Code §§ 4000 and following) detailing general compounding by a pharmacy.

The purpose for amending the above sections is to remove redundancies between the requirements for general compounding and sterile injectable compounding as well as to ensure consistent sequencing of related requirements contained in both Articles.

This proposal will provide uniformity in compounding for California consumers. Below is a summary of each change as well as a brief justification for each change.

Repeal 16 CCR 1716.1 – Compounding Unapproved Drugs for Prescriber Office Use.

The provisions in 1716.1 are now included within other sections including 1735 & 1735.2 of the regulation proposal.

Repeal 16 CCR 1716.2 – Records Requirement – Compounding for Future Furnishing.

The provisions in 1716.2 are now included in other section 1735.3 of the regulation proposal.

Add 16 CCR 1735 – Compounding in Licensed Pharmacies

This new section will define the activities that constitute. These activities were defined by the workgroup, which included members of industry, board staff and board members.

Add 16 CCR 1735.1 – Compounding Definitions

This new section defines the terms “integrity”, “potency”, “quality”, and “strength” referenced throughout the regulation proposal for clarity and ease-of-reference.

Add 16 CCR 1735.2 – Compounding Limitations and Requirements

This new section places limitations on the conditions for compounding including anticipatory use. In addition, this section allows for anticipatory compounding under specified conditions. This section contains the provisions previously contained in section 1716.1 and section 1716.2, which is being repealed in this proposal and specifies the general requirements for compounding. Those requirements include the requirement to maintain a master formula, storage requirements and expiration date requirements. In addition this section now requires the completion of a self-assessment form, which is incorporated by reference in this section. This self-assessment form is to assist pharmacies in increasing their compliance with legal requirements and therefore increase public safety as a result of this compliance. Additionally, the proposal would make the pharmacy inspection process more meaningful and provide relevant information to pharmacies and their pharmacist-in-charge (PIC).

Add 16 CCR 1735.3 – Records of Compounded Drug Products

This new section details the pharmacy records requirements for each compounded drug, record requirements for acquisition, storage and destruction for products used in compounding, specifies that all drug products must be obtained from reliable suppliers and specifies that all records required must be maintained for at least three years. Some of these requirements were previously included in section 1716.2 which is being repealed in this proposal. It is necessary to require the pharmacy to maintain records for acquisition, storage and destruction of products to confirm that drug products are obtained from reliable suppliers, and in the event of a product recall, allow the pharmacy to identify products affected and remove them from inventory. The records retention period of three years is consistent with all other pharmacy related records retention throughout pharmacy law.

Add 16 CCR 1735.4 – Labeling of Compounded Drug Products.

This new section requires that the labeling of the product comply with Business and Professions Code section 4076 as well as specifies that the labeling requirements for compounded drugs must include the generic name of the principle active ingredients as well as a statement that the product is compounded. This requirement provide for full consumer notification and will enable the consumer to identify any potential allergies to ingredients used.

Add 16 CCR 1735.5 – Compounding Policies and Procedures

This new section establishes and defines the content of the policy and procedure manual that must be maintained by a pharmacy that compounds medications. The procedure manual is necessary to ensure that the pharmacy has established procedures for procurements, methodologies of the formulation and compounding of drugs as well as procedures for facilities and equipment cleaning, maintenance and operation.

Add 16 CCR 1735.6 – Compounding Facilities and Equipment

This new section requires that the pharmacy maintain written documentation regarding the facilities and equipment used and specifies that all equipment (where applicable) shall be calibrated and the results documented in accordance with the manufacturers' specifications. This is necessary to ensure that equipment used in compounding is used and maintained appropriately.

Add section 16 CCR 1735.7 – Training of Compounding Staff

This new section requires that the pharmacy maintain written documentation and an ongoing evaluation process to demonstrate that pharmacy personnel assigned compounding duties are trained and possess the necessary skills. This requirement will ensure that only qualified personnel compound medicine for California consumers.

Add section 16 CCR 1735.8 – Compounding Quality Assurance

This new section requires that the pharmacy include a written quality assurance plan designed to monitor and ensure the integrity, potency, quality and labeled strength of compounded drug products. This section also specifies the required elements of the plan. This requirement will protect consumers by ensuring that a pharmacy that compounds medications has an appropriate quality assurance plan in place.

Amend 16 CCR 1751 – Sterile Injectable Compounding – Compounding Area

This section is amended to clarify that pharmacies that compound sterile injectable products must comply with Article 4.5 and Article 7. This amendment is necessary as relevant requirements were consolidated into Article 4.5 to remove redundancies within the two articles.

Amend 16 CCR 1751.1 – Sterile Injectable Recordkeeping Requirements

This section is renumbered from 16 CCR 1751.3 to 1751.1 to conform with the sequence of similar subject areas of Article 4.5 (16 CCR 1735 – 1735.8).

Amend 16 CCR 1751.2 – Sterile Injectable Labeling Requirements

This section is amended to include the specific labeling requirements contained in Business and Professions Code section 4076 as well as the labeling requirements specified in 16 CCR 1735.4 to ensure consistency.

Amend 16 CCR 1751.3 – Sterile Injectable Policies and Procedures

This section is renumbered from 16 CCR 1716.02 and is consolidated to reduce confusion. In addition it was reordered to conform with the sequence of similar subject areas in Article 4.5. Subsection (c) was moved and slightly modified from former section 16 CCR 1751.1, to consolidate similar provisions.

Amend 16 CCR 1751.4 – Facility and Equipment Standards for Sterile Injectable Compounding

This section is renumbered from 16 CCR 1751.01 and is consolidated with 16 CCR 1751.1. In addition subsection (d) was moved and is slightly modified from former section 16 CCR 1751.1, to consolidate similar provisions.

Amend 16 CCR 1751.5 – Sterile Injectable Compounding Attire

This section is renumbered from former section 16 CCR 1751.4.

Amend 16 CCR 1751.6 – Training of Sterile Injectable Compounding Staff, Patient and Caregiver

This section is renumbered from former section 16 CCR 1751.5.

Amend 16 CCR 1751.7 – Sterile Injectable Quality Assurance and Process Validation

This section specifies that any pharmacy engaged in sterile injectable compounding must include a written quality assurance plan as part of its written policies and procedures and that batch-produced sterile to sterile transfers are subject to periodic testing through process validation for sterility as determined by the pharmacist-in-charge and described in the written policies and procedures. This is necessary to ensure the integrity of compounded product and is an important patient safety measure.

Amend 16 CCR 1751.8 – Sterile Injectable Compounding Reference Materials.

This section is renumbered from former section 16 CCR 1751.9 and was slightly modified to use consistent language throughout Article 7.

Factual Basis

In 2004 the Board of Pharmacy formed a Workgroup on Compounding comprised of board members, board staff and industry representatives. The workgroup recognized that current pharmacy regulations addressing compounding only govern the physical circumstances, procedures and record keeping requirements for general compounding and do not address quality, strength or purity.

The Board adopted regulations in Article 7 of Division 17 of Title 16 of the California Code of Regulations (commencing with Section 1751) to implement provisions for pharmacies that compound sterile injectable products as required in Business and Professions (B&P) Code Section 4127. As there are no similar provisions in regulation for general compounding, this amendment would establish the parameters and provide uniformity for pharmacies that complete general compounding.

Records, labeling and quality assurance are needed for any product a pharmacy compounds, even if the pharmacy rarely compounds medications. The level of recordkeeping and quality assurance required, as specified in these regulations, depends upon the frequency and volume of medicine compounded. The pharmacy that rarely compounds medicine or does so to a limited extent may provide most of the

recordkeeping on the prescription document itself. When larger volumes of medicine are compounded, the Board expects more recordkeeping and higher quality assurance. This proposal distinguishes between the two levels.

The current practice of compounding pharmacies includes the maintenance and documentation of records. This regulation standardizes these general practice standards for recordkeeping and procedures. This regulation also specifies the quality assurance process that must be completed to ensure each product meets acceptable quality, purity, and strength requirements.

Completing the self-assessment form would allow the pharmacist-in-charge (PIC) to increase the pharmacy's compliance with legal requirements without awaiting board inspection. The benefit to the public when a wholesaler is in compliance with the law is significant.

An inspector conducting an inspection is frequently asked questions regarding aspects of the inspections as well as clarifications and requirements of pharmacy law. This self-assessment form would provide an easy reference guide to the PIC when an inspector is not available.

Below is a brief description of the relevant sections of state and federal law.

Business and Professions Code section 4005 provides that board with the authority to adopt rules and regulations.

Business and Professions Code section 4036 defines the term "pharmacist".

Business and Professions Code section 4037 defines the term "pharmacy".

Business and Professions Code section 4051 specifies that it is unlawful for any person to manufacture, compound, furnish, sell or dispense any dangerous drug or device or to dispense or compound any prescription pursuant to a prescriber unless he or she is a pharmacist.

Business and Professions Code section 4052 specifies permissible procedures by a pharmacist.

Business and Professions Code section 4059 specifies the conditions for furnishing dangerous drugs and devices upon a prescription as well as exemptions to the requirement.

Business and Professions Code section 4076 specifies the labeling requirements for prescription containers.

Business and Professions Code section 4081 specifies the requirements for records of dangerous drugs and devices.

Business and Professions Code section 4127 requires the board to adopt regulations establishing standards for sterile injectable compounding.

Business and Professions Code section 4127.7 specifies the requirements for compounding sterile injectable products from nonsterile ingredients.

Business and Professions Code section 4332 specifies that it is a misdemeanor to fail or refuse to maintain or produce records.

Health and Safety Code section 18944 requires state agencies to adopt regulations for publication in titles of the CCR containing other regulations of that agency to identify, the appropriate sections of the California Building Standards Code.

Underlying Data

This proposal is based upon recommendations from the Workgroup on Compounding as well as public comment to those recommendations at several board meetings and Licensing Committee Meetings

- (1) Minutes from Compounding Workgroup Meeting - March 3, 2004
- (2) Minutes from Compounding Workgroup Meeting - June 9, 2004
- (3) Minutes from Compounding Workgroup Meeting - September 22, 2004
- (4) Minutes from Compounding Workgroup Meeting - December 1, 2004
- (5) Minutes from Board Meeting - January 19 & 20, 2005

Business Impact

This regulation will not have a significant adverse economic impact on businesses. This initial determination is based on the following facts or evidence/documents/testimony:

The Board of Pharmacy is aware that pharmacies that compound medicine will incur the cost of end-product testing. The estimated costs for such testing are about \$100.00 per test. This is a one-time cost as long as the compounding process remains the same.

Specific Technologies or Equipment

This regulation does not mandate the use of specific technologies or equipment.

Consideration of Alternatives

No reasonable alternative to the regulation would be either more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the proposed regulation.